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81.(New) ~~The method of claim 83 wherein the struts are arranged in serpentine configurations.~~

REMARKS

This amendment is submitted as part of a Request for Continued Examination in response to the Final Office Action dated October 8, 2002 in which claims 61, 64, 65 and 68 were rejected. Applicant notes that a Notice of Appeal had been filed in the instant application on January 31, 2003. Claims 61 and 65 have been amended. New claims 69-84 have been added. No new matter has been added.

112 Rejection

Claims 65 and 68 are rejected under 35 USC 112, second paragraph as failing to particularly point and distinctly claim the subject matter which applicant regards as the invention. The Office Action objects to the use of the term 'solid' to describe the wall of the stent. As part of the amendments to claim 65, Applicant has eliminated the language in question.

103(a) Rejection – Fontaine and Alfidi

Claims 61, 64, 65 and 68 are rejected under 35 USC 103(a) as being unpatentable over Fontaine (US 5370683) in light of Alfidi et al (US 3868956).

Claim 61 is directed to a stent formed from an open-ended tube which has a wall with a multiplicity of holes formed therethrough. The holes have been formed by removal of material from the wall. The tubular wall is defined by a plurality of struts which bound the holes. Each of the struts has a cross-section of oval shape. Fontaine is directed to a stent formed from wire which is wrapped around a mandril (see, for example, the abstract of Fontaine). Fontaine does not disclose or suggest making a stent which is formed from a tube, where the openings in the wall of the stent are made via the removal of wall material. Moreover, as acknowledged in the Office Action, Fontaine does not disclose oval struts. Alfidi is relied upon for the disclosure of oval struts. Alfidi, does not, however, supply the missing teaching concerning the presence of a tube having holes which have been formed by removal of material from the wall of the tube. The device shown in Figs. 11-13 of Alfidi is a wire coil (see col. 7, line 67 – col. 8, line 18).

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There is no disclosure that it is made by removing materials from a tube. Therefore, even if the proposed combination is made, the combination still does not teach or suggest all of the elements of the instant claim.

Furthermore, Applicant does not see the motivation to use the oval wire of Alfidi with the stent of Fontaine in that the welding together of adjacent sections of oval wire which is oriented with the long side facing inward and outward would be expected to be more difficult than welding together wire of rectangular cross-section. In the latter case, a larger area of contact between adjacent struts would result as compared with the former case. Moreover, if one were motivated by increasing surface contact area of strut with a vessel wall, one would be expected to use rectangular struts which would have an even greater area of contact as compared with oval struts.

Therefore, claim 61 and claim 64 dependent therefrom are patentable over the proposed combination. Withdrawal of the rejection is respectfully requested.

Independent claim 65 is directed to a stent comprising an open-ended elongate tube having a generally circumferential wall with a multiplicity of interconnected curvilinear struts formed in the wall of the tube. The struts are disposed about a multiplicity of through-holes in said wall. Each of the through-holes is bounded by struts. Each of the struts has an oval cross-section with a short diameter corresponding substantially to the thickness of the wall.

As discussed above with respect to claim 61, the Fontaine stent is made from a wire which is wound around a mandril. Fontaine does not disclose a stent having a generally circumferential wall with a multiplicity of interconnected curvilinear struts formed in the wall of the tube. To the extent that the Fontaine stent may be considered to have 'struts', the 'struts' are not 'formed in the wall of the tube'. Rather, they are formed from a filament of wire. The stent of Figs. 11-13 of Alfidi, as discussed above, is in the form of a coil of wire and lacks disclosure of struts formed in a wall. As such, Alfidi does not provide the missing teaching concerning the presence of struts which are formed in the wall of the tube. Therefore, even if the proposed combination is made, the combination still does not teach or suggest all of the elements of the instant claim.

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Furthermore, Applicant does not see the motivation to use the oval wire of Alfidi with the stent of Fontaine for the reasons discussed above with respect to claim 61.

Therefore, claim 65 and claim 68 dependent therefrom are patentable over the proposed combination. Withdrawal of the rejection is respectfully requested.

103(a) Rejection – Klein and Alfidi

Claims 61, 64, 65 and 68 are rejected under 35 USC 103(a) as being unpatentable over Klein (US 5593442) in light of Alfidi et al (US 3868956). In order to sustain a section 103 rejection, there must be a motivation to make the proposed combination (see, for example, MPEP 2143.01). There is no motivation for making the proposed combination. Simply put, nothing in Klein suggests that improvement in contact between the struts and the vessel is needed in the Klein stent. Klein, in fact, states at col. 5, lines 43-45, that the rings of the Klein stent 'will continue to provide significant contact with and support of the inner wall of the body lumen' thereby leading one of ordinary skill in the art to believe that the vessel contact of the Klein stent is adequate. Moreover, the struts of the Klein stent appear to be rectangular. See, for example, Figs. 1, 1a, 2 and 4a. A strut with a rectangular cross section of width 'd' would have an even greater contact area as compared with a strut with an oval cross-section whose width is 'd'. Therefore, by modifying the Klein stent with oval struts, the contact area of the stent would be decreased, which is contrary to the stated purpose of oval struts as discussed in Alfidi. Because there is no motivation to make the proposed combination, the section 103 rejection is inappropriate. Withdrawal of the rejection is respectfully requested.

102(b) Rejection - Alfidi

Claims 61, 64, 65 and 68 are rejected under 35 USC 102(b) as being anticipated by Alfidi et al.

Independent claim 61 includes the recitation that the struts completely bound the holes. This limitation is also not found in Alfidi – to the extent, for the sake of argument, that Alfidi has 'holes' and 'struts', the 'struts' do not completely bound the 'holes' because of the coil-like nature of the stent. Also, claim 61 includes the recitation that the tube has a wall with a multiplicity of holes formed therethrough, the holes having been formed by removal of material

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from the wall. This limitation is not disclosed in Alfidi. To the extent, for the sake of argument, that Alfidi discloses 'holes', the 'holes' are not formed by removal of material from the wall – rather, they are formed by the winding of a wire. Therefore, because not all of the elements of independent claim 61 are present in Alfidi, Alfidi does not anticipate either claim 61 or claim 64 dependent therefrom.

Independent claim 65 includes the limitation that each of the through-holes is bounded completely by struts. This limitation is not present in Alfidi because, as discussed above, to the extent, for the sake of argument, that Alfidi has 'through-holes', the 'through-holes' are not bounded completely by struts because of the coil design of the stent. The claim also includes the recitation that there is a multiplicity of interconnected curvilinear struts formed in the wall of the tube. To the extent, for the sake of argument, that the Alfidi stent has 'struts', the struts are not formed in the wall. The term 'formed in the wall' requires the presence of a wall first, followed by the formation of a strut in the preexisting wall. In the case of Alfidi, there is no pre-existing wall in which a strut may be formed. Therefore, because not all of the elements of independent claim 65 are present in Alfidi, Alfidi does not anticipate either claim 65 or claim 68 dependent therefrom.

FORMALITIES

To the extent a Petition for Extension of Time is necessary and has not otherwise been filed, Applicant requests that this be considered as such a petition. To the extent that any fee is due with this communication and has not otherwise been paid, please charge the fee to Deposit Account number 22-0350.

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CONCLUSION

In light of the above comments, Applicant requests that the rejections to the claims be withdrawn and that a notice of allowance be issued.

Respectfully submitted,

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Marked-Up Claims

New claims 69-84 have been added.

The claims have been amended as follows:

61.(Twice Amended) A [balloon-expandable vascular or endoluminal] stent [adapted for deployment in a vessel or tract of a patient to maintain an open lumen therein, comprising a scaffold] formed from an [single] open-ended tube having a first end and a second end, [solid tubular wall with] the tube having a wall with a multiplicity of [through-holes] holes formed therethrough between the first and second ends, the holes having been formed by removal of material from the wall, [in the] the tubular wall defined by a plurality of struts completely bounding said [through-holes] holes; each of said struts having [an optimized] a cross-section of oval shape with a short diameter corresponding substantially to the thickness of said wall so that the long sides of the oval lie at the outside and the inside of the tube wall at the respective strut[, to enhance flexibility of the stent, ease advancement of the stent through a lumen of the vessel or tract for deployment at a target site therein, protect the balloon of a balloon catheter when the stent is tightly crimped thereon, and enhance expansion of the stent during deployment while maintaining its capability to withstand compression in response to recoil of the wall of the vessel or tract following deployment].

65.(Twice Amended) A [balloon-expandable] stent having a first end and a second end, the stent [for deployment in a patient's vessel, tract or duct to maintain an open lumen therein,] comprising an open-ended elongate tube having a generally circumferential [solid] wall[, there being a multiplicity of interconnected curvilinear struts formed in the wall of said tube, [and thereby] the struts [defining] disposed about a multiplicity of through-holes in said wall, each of said through-holes being bounded completely by struts; each of said struts having an oval cross-section with a short diameter corresponding substantially to the thickness of said wall[, whereby to enhance the longitudinal flexibility of the stent, ease advancement of the stent through a lumen of the vessel, tract or duct for deployment at a target site therein, protect the balloon of a balloon catheter when the stent is tightly crimped thereon for advancement or expanded therefrom by inflation of the balloon, and enhance expansion of the stent during deployment while maintaining its capability

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to withstand compression in response to recoil of the wall of the vessel, tract or duct following deployment of the stent as a scaffold in support thereof].